

**Expert Report of Laxmaiah Manchikanti, M.D.**

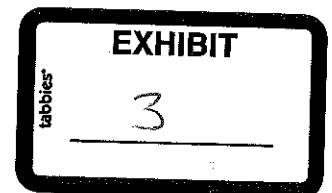
**1. Background and Qualifications:**

I am an anesthesiologist and interventional pain management specialist actively licensed as a physician in Kentucky, Illinois, and Indiana. In 1966 I graduated from Dharmavant Hindi Higher Secondary School, in Hyderabad, India where I obtained my pre-medical education. I then attended Gandhi Medical College at Osmania University in Hyderabad, India from 1966 to 1972 where I obtained my medical degree. From 1972 to 1976, I completed an internship in internal medicine and a residency in anesthesiology at Gandhi Hospital in Secunderabad, India.

From 1977 to 1978, I continued my residency training in anesthesiology with the Department of Anesthesiology at Youngstown Hospital Association at North Eastern Ohio Universities College of Medicine in Youngstown, Ohio, before completing my residency training at Allegheny General Hospital in Pittsburgh, Pennsylvania from 1978 to 1979. Following residency, I completed a fellowship in anesthesiology and critical care medicine at the University of Pittsburgh School of Medicine in Pittsburgh, Pennsylvania from 1979-1980.

I have been certified by the American Society of Anesthesiologists since 1980, with subspecialty certification in Pain Medicine by the American Board of Anesthesiology since 1993. I have also been a Diplomate with the American Board of Pain Medicine since 1993 and a Fellow of the Interventional Pain Practice with The World Institute of Pain since 2002. I am also a Diplomate and Secretary/Treasurer of the American Board of Interventional Pain Physicians.

I have held hospital staff privileges with Lourdes Hospital in Paducah, Kentucky since July of 1980, Western Baptist Hospital in Paducah, Kentucky since February of 1985, Heartland Regional Medical Center in Marion, Illinois since April 2001, Harrisburg Medical Center in Harrisburg, Illinois from July 1988 to 1991, Massac Memorial Hospital in Metropolis, Illinois



from December 1986 to December 1987. In 1985 and 1992, I was also the Director of the Department of Anesthesiology at Lourdes Hospital.

Currently, I am the Medical Director of several pain management facilities, including the Pain Management Center of Paducah, the Ambulatory Surgery Center in Paducah, Kentucky, the Pain Management Center of Marion, and Pain Care Surgery in Marion, Illinois. I am also the founder, Chairman of the Board, and Chief Executive Officer of the American Society of Interventional Pain Physicians (ASIPP), the Society of Interventional Pain Management Surgery Centers (SIPMS), and many state Societies of Interventional Pain Physicians. I also founded the *Pain Physician* Journal, ABIPP, and the ASIPP Foundation.

I have published and served on editorial boards for journals in areas including, but not limited to, pain medicine practice management, pain medicine, interventional pain medicine, interventional techniques in chronic spinal pain, and anesthesiology. I am also a member of a number of professional organizations, including, but not limited to, the American Society of Interventional Pain Physicians, the Kentucky Society of Interventional Pain Physicians, the Illinois Society of Interventional Pain Physicians, the Society of Interventional Pain Management Surgery Centers, and the International Association for the Study of Pain.

A copy of my *curriculum vitae*, more fully setting forth my experience and professional accomplishments, is attached as Exhibit 1. Any publications I have authored in the previous 10 years are listed on my *curriculum vitae*.

## **2. List of Cases**

I have testified as an expert in trial or by way of deposition in the past four (4) years in the following case:

*Jennifer Darlene Bunch and Robert Bunch* vs. Jeffrey Landman, M.D. and Virtual Radiology, PC; Law Office of Barry E. Weathers, Nashville, Tennessee; Case No. 06C-

2495; October 21, 2010; Case went to trial July 2014.

**3. Facts and Data Considered in Forming My Opinions:**

In forming my opinions, I have generally relied on my education, training, experience, and the materials I have reviewed. The following is a brief summary of the facts I rely upon in forming my opinions regarding Box Hill Surgery Center, LLC, Ritu Bhambhani, M.D., LLC, Ritu T. Bhambhani, M.D., LLC (collectively, “Box Hill Defendants” or “Box Hill”), and any agents or employees of the same.

**a. Background for Dr. Bhambhani and Box Hill Surgery Center**

Dr. Bhambhani is board certified in anesthesiology and pain medicine. She graduated from medical school in 1994, and then did her post graduate training, including a residency and fellowship in anesthesiology and pain medicine, at the Cleveland Clinic in Ohio. She then obtained her Maryland license and began practicing anesthesiology and pain medicine in Maryland in 2000. She was employed as an anesthesiologist by Harford County Ambulatory Surgery Center (in Maryland) starting in 2003, before opening Box Hill Surgery Center in 2008. Box Hill Surgery Center is a standalone ambulatory surgery center in Abingdon, Harford County, Maryland. Dr. Bhambhani is the sole owner and only regular physician at Box Hill, where she is also the Medical Director. Throughout the years, Dr. Bhambhani has practiced anesthesiology and pain management, including interventional techniques to relieve pain like the ones at issue in this case. In my opinion, Dr. Bhambhani is experienced and well qualified to provide pain management services, among other things. Dr. Bhambhani is also qualified as an anesthesiologist and pain medicine expert to make decisions regarding the purchase of medications for a medical practice.

**Exhibit 2**

- FDA Form 483 to NECC
- FDA Form 483 to ARL
- Massachusetts BOP/DPH Preliminary Investigative Report
- Report from the Massachusetts Board of Pharmacy's May 2011 inspection of NECC
- NECC Indictment
- Congressional Memo: "FDA's Oversight of NECC and Ameridose: A History of Missed Opportunities?"
- NECC Environmental Monitoring Results
- NECC Cleaning Logs
- NECC Standard Operating Procedures
- Liberty clean room punch list (Ex. 1202)
- Logged Formula Worksheets for the Three Contaminated Lots of MPA
- Daily Fill Logs for the Recalled Lots of MPA
- ARL Testing Results for Three Recalled Lots of MPA
- Video from NECC's Surveillance Cameras
- Video from Inspections of NECC's Facility in December 2012 and July 2014
- Disks containing audio from Barry Cadden's Training for Sales Personnel
- Floorplan Showing the Layout of NECC's Facility
- Scientific Air Analysis Testing Results from 2011 and 2012
- Monthly Cleaning Logs Completed by UniClean Technicians
- Documents regarding a 2012 complaint to NECC from Massachusetts Ear and Eye Institute (the customer complaint)
- Joe Cabaleiro, RPH, New England Compounding Center Indictment, Int' J. Phar Compounding, March- April 2015, at 94.
- ASHP Guidelines (Ex. 1327)
- NECC Quality Assurance Report Cards for 2011 and 2012
- Notes from Keith St. John and Ian Wallis from conversations with NECC's Joe Connolly
- Drug Recall Charts
- NECC Customer List
- FDA Warning Letter to NECC-12/06 (Ex. 1309)
- NECC Letter (1/5/07) to FDA in Response to FDA 2006 Warning Letter (Ex. 1310)
- FDA Letter (10/31/08) to NECC in Response to NECC Response Letter (1/5/07) to FDA 2006 Warning Letter (Ex. 1311)
- FDA Email (7/17/12) Regarding Colorado Cease and Desist Order (5/10/11) and FDA Not Taking Further Action Against NECC at this time (Ex. 1312)
- Emails between NECC and UniClean (Deposition exhibits 422, 424, 426-431)
- Photographs of NECC's standing autoclave
- Photographs of the gaps in ceiling of cleanroom 1
- PCCA formula for compounding MPA
- NECC advertising materials provided to some customers
- New York Times article reporting on several Johnson & Johnson product recalls

- US Compounding, Inc. voluntary recall; 2014-2015 FDA inspections of US Compounding, Inc.; 2012 and 2015 US Compounding, Inc. website printouts
- USP 797
- USP 71
- USP 85
- Expert Report/Declaration of Dr. Philip Austin, Ph.D.
- Deposition of Philip Austin, Ph.D.
- Deposition/Report of Keith St. John
- Deposition/Report of Ian Wallis
- Deposition/Report of Ray Schneider
- Deposition/Report of Sheldon Bradshaw
- Deposition/Reports of Brian Reisetter
- Deposition of William Mixon
- Deposition/Report of Robert Guardino
- Deposition of Stephen O'Neill
- Deposition of Francis McAteer
- Deposition of Michael Cotugno
- Deposition of Edwin Cardona
- Deposition of Ricardo Dos Santos
- Deposition of Edgardo Camacho
- Deposition of Suneela Mistry
- Deposition of Jeffrey Erickson
- Deposition of George Pollick
- Deposition of Robert Kaiser
- Deposition of Michael Debeau
- Deposition of Thomas C. Kupiec
- Deposition of Tommy Means
- Deposition of Samuel Penta
- Depositions of YuZon Wu
- Deposition of Lucy Wilson, M.D.
- Deposition of Joseph Alessandrini, R.Ph.
- Deposition of Mario Giamei
- Deposition of Lisa Cadden
- Deposition of Steven Higgins
- Deposition of Owen Finnegan
- Deposition of Stephen Haynes
- Deposition of Cory Fletcher
- Deposition of Annette Robinson
- Deposition of Belmira Carvalho
- BHSC Responses to Request for Production of Documents (Bates 1-1586) including, among other things, AAAHC certifications and policies and procedures
- Deposition Transcript/Exhibits of Ritu Bhambhani, MD- Box Hill Surgery Center
- Deposition Transcript/Exhibits of Andrew Vickers, RN- Box Hill Surgery Center
- Deposition of Kimberly Brockmeyer

- Deposition of Barbara Wagner
- Expert Report of David Chason, MD
- Expert Report of Lloyd Saberski, MD
- Expert Report of Shmuel Shoham, MD
- Deposition of Lloyd Saberski – Circuit Ct Baltimore County, MD-Consolidated Cases
- Deposition/Report of Lawrence Winikur
- Deposition (Rule 31) of Faye Menter- Cumberland Valley Surgery Center
- Deposition (Rule 31) of Donald Bartnick- Annapolis Surgery Center
- Deposition (Rule 31) of Susan Calhoun-Peninsula Orthopaedics
- Deposition (Rule 31) of Charlotte Rhew-James Davis (Duke) Ambulatory Surgery Center
- Deposition (Rule 31) of Diana Holt-Premier Orthopedics & Sports Medicine-TN
- Deposition (Rule 31) of Laura Ross- Adams, DO-The Ross Center
- Deposition (Rule 31) of Kimberly Mason-University of Tennessee Medical Center
- Deposition (Rule 31) of James Cathey-East Tennessee Children's Hospital
- Deposition (Rule 31) of Noli Dominguez-Central Jersey Orthopedics
- Deposition (Rule 31) of Rhonda Proscia-The Montclair Orthopaedic Group- NJ
  
- **Angela Farthing, Patient**  
Complaint  
Defendants, Bhambhani & Box Hill's Answer to Complaint  
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.  
Defendant: Certificate of Merit/Report – David Maine, M.D.  
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center Bates nos.: 1-452
  
- **Linda Torbeck, Patient**  
Complaint  
Defendants, Bhambhani & Box Hill's Answer to Complaint  
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.  
Defendant: Certificate of Merit/Report – David Maine, M.D.  
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center Bates nos.: 1-148
  
- **Belinda Dreisch, Patient**  
Complaint  
Defendants, Bhambhani & Box Hill's Answer to Complaint  
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.  
Defendant: Certificate of Merit/Report – David Maine, M.D.  
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center (Bates nos.:1-187)
  
- **Teresa Davis, Patient**  
Complaint  
Defendants, Bhambhani & Box Hill's Answer to Complaint  
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.  
Defendant: Certificate of Merit/Report – David Maine, M.D.  
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center Bates nos.: 1-86

- **Edna Young, Patient, Deceased Evelyn Bowman, PR of Estate**  
Complaint  
Defendants, Bhambhani & Box Hill's Answer to Complaint  
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.  
Defendant: Certificate of Merit/Report – David Maine, M.D.  
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center Bates nos.: 1-82
- **John Millhausen, Patient, Deceased, Mary Joyce Armetta, PR of Estate**  
Complaint  
Defendants, Bhambhani & Box Hill's Answer to Complaint  
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.  
Defendant: Certificate of Merit/Report – David Maine, M.D.  
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center Bates nos.: 1-26
- **Bahman Kashi, Patient, Deceased, Kiumarc Kashi, PR of Estate**  
Complaint  
Defendants, Bhambhani & Box Hill's Answer to Complaint  
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.  
Defendant: Certificate of Merit/Report – David Maine, M.D.  
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center Bates nos.: 1-24
- **Brenda Rozek, Patient, Deceased, Meghan Handy, Individually and as Surviving Child & PR of Estate**  
Complaint  
Defendants, Bhambhani & Box Hill's Answer to Complaint  
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.  
Defendant: Certificate of Merit/Report – David Maine, M.D.  
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center Bates nos.: 1-39